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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,999	12/07/2001	John D. Dobak III	2050/1 D1	5765

27774 7590 12/17/2003

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EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

8

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/008,999

Applicant(s)

DOBAK, JOHN D.

Examiner

DAVID J ISABELLA

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyd, et al (5799661) in view of Ginsburg (5837003).

Boyd et al discloses a coronary bypass procedure comprising the steps of cooling the the heart of a patient to less than 35 degrees C using a heat transfer element. Boyd forms a fluid communicating graft between the blood supply and the coronary artery and the patient's blood is oxygenated in the patient's lungs by the patient's heart or intracorporeal pump. Examiner contends that the method for cooling the heart, as disclosed by Boyd would inherently cool the body to a temperature below 35 degrees.

The heat exchanger of Boyd et al is a topical device. Ginsburg teaches a method and apparatus for controlling body temperature in situ with a heat exchanger designed to be inserted into a blood vessel of a patient. Ginsburg method includes inducing the condition of artificial hypothermia depending on the desired applications. To control the body temperature of a patient undergoing coronary bypass procedure by using a heat exchanger designed for insertion into the blood vessel of the patient as taught by Ginsburg, instead of the topical exchanger thereby would have been obvious to one with ordinary skill in the art based on substitution of equivalent methods for

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artificially inducing hypothermia. Moreover, one of ordinary skill in the art would use the catheter method as taught by Ginsburg to reduce the problems and drawbacks related to thermal shock to the myocardial tissues at the time of the invention thereof.

Claim 2, see column 4 of Ginsburg.

Claim 3, see column 1, lines 28+ of Ginsburg.

Claims 4-9, see columns 9 & 10 of Boyd, et al.

Claim 10 see column 4 of Ginsburg.

Claims 11-17 are directed to method steps for arresting the heart or placement of the heat exchanger. The use of chemicals and electrical charge in arresting and/or stimulating the heart is well known in the art and the single use or the combination of electrical charge and chemicals in stopping or starting the beat of the heart do not form the basis of this invention. The placement of the heat exchanger in a venous vasculature (eg vena cava or vein) would have been obvious to one with ordinary skill in the art based upon surgical considerations. See column 5-6 of Ginsburg. Claim 1 recites that the blood is oxygenated either by the patient's heart or an intracorporeal pump. Applicant's arguments to this point is not commensurate with the scope of the claim. Contrary to applicant's arguments, examiner has provided some teachings and motivation in the art to replace the topical cooling apparatus of Boyd with an indwelling catheter as taught by Ginsburg.

Claim 18, see column 5, lines 58+ of Ginsburg.

Claims 19-22 see figures 5 and 11 of Ginsburg. For the interior surface irregularities, see figure 6 which clearly shows a polygonal configuration designed for

fluid flow therein. Note, column 7, lines 20+ of Ginsburg discloses that some embodiments provide an increased surface area through which the heat transfer may take place.

Claim 23, see columns 7-8 of Boyd et al.

Claim 24, see column 1, lines 28+ of Ginsburg.

Claim 25, see column 9, lines 40+ of Boyd, et al.

### ***Response to Arguments***

Applicant's arguments filed 10/12/03 have been fully considered but they are not persuasive. See examiners comments in the body of the rejection.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J ISABELLA  
Primary Examiner  
Art Unit 3738

dji  
December 15, 2003